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Daniel H Shulman
Mayer Brown & Platt
PO Box 2828
Chicago, IL 60690-2828

EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/04/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/582,522

Applicant(s)

MAOR ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-31 are pending. Claims 7-8 are withdrawn from consideration, as they are directed toward non-elected subject matter. The Amendment filed 3/17/03, Paper No. 21, amended claims 1, 5, 25-26 and 28.

Applicant's arguments with respect to claims 1-6 and 9-31 have been considered but are moot in view of the new ground(s) of rejection. However, to the extent that the arguments may be relevant to the instant rejection, the Examiner will address them.

The Restriction Requirement of Paper No. 7, mailed 8/14/01, is maintained. In Paper No. 8, received 9/14/01, Group I, the composition claims, were elected. Thus, claims 7-8 are withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/17/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 3 and 23 contain the trademark/trade name tween-20, oleth-20, tween-80, ceteth-20. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe nonionic solubilizers and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 4-5, 10, 13, 14, 19, 20, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biener (4,943,432).

The instant invention is directed to a gel composition comprising 34.1-80% water having a total dissolved salt value between 25-40% and having an ion composition comprising 36,000-40,000mg/l Calcium, 320,000-370,000mg/l Chloride, 90,000-95,000mg/l Magnesium, 1300-1500mg/l Potassium, 1500-2500 mg/l Sodium, 11,000-12,000 mg/l Bromide, a solubilizer, a gelling agent/viscosity modifier, and deionized water to 100%.

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Biener is directed to compositions that contain a salt mixture (title and abstract). The composition can be in gelled form (abstract). For a salt composition that comprises concentrations of calcium, chloride, magnesium, potassium, sodium and bromide, see column 2, lines 10-47. For a salt concentration within the instantly claimed range in a carrier such as water see column 3, lines 53-61. For gelling agents or viscosity modifiers see natural gums and cellulose esters and ethers at column 4, lines 9-15. For a transparent gel, which is considered equivalent to a clear gel, see column 4, lines 15-16. The phrase "in an amount not to exceed 'x'% w/w" includes zero as a lower limit. Therefore, claims 5, 18, 19, 22, and 28 do not require a hydrophilic active agent, a hydrophobic active agent or a fragrance.

The composition can contain 1-20% glycol and/or glycerin at column 4, lines 20-22, both of which are solubilizers. The compositions can contain salicylic acid, an alpha-hydroxy acid, which is a known antioxidant, at column 3, lines 38-41.

The reference teaches that it is advantageous to vary the concentration of the invention's salt solutions according to the patient's skin type. The concentration may generally range from 0.1-34%. The gel is prepared by dissolving the composition in water.

The reference does not teach the preferred concentration of sodium and preferred percent weights of water.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the concentration of sodium and water in the composition of Biener because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (In re Aller,

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105 USPQ 233), and because of the expectation of achieving a composition that has the maximum therapeutic effect on a patient's skin type.

Claims 3, 6, 9, 11, 12, 16, 18, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biener as applied to claims 1-2, 4-5, 10, 13, 14, 19, 20, 29 above, and further in view of Thompson et al. (5,425,954).

Biener is applied as taught above. The reference does not teach preferred solubilizers, antioxidants, hydrophobic actives, or fragrances.

Thompson et al. teach compositions for the treatment of psoriasis. Perfumes are taught as composition additives. Vitamin E/tocopherol acetate is taught as preventing the oxidation of fatty acids, thereby protecting lipids and lipoproteins in cell membranes which allows cells to retain water binding capacity and prevents dry skin. Ceteth-20 is taught as a lubricant. See Col. 3, lines 9-24; Col. 5, line 44-Col. 7, line 39.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the vitamin E and ceteth-20 taught by Thompson et al. to the composition of Biener because of the expectation of achieving a composition that prevents oxidation and drying out of the skin and because of the expectation of achieving a composition that has lubricant properties, and thus, smooth feel when applied to the skin.

Claims 15-17, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biener as applied to claims 1-2, 4-5, 10, 13, 14, 19, 20, 29 above, and further in view of The Handbook of Cosmetic Science and Technology.

Biener is applied as discussed above. The reference lacks preferred thickeners and fragrances.

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The Handbook of Cosmetic Science and Technology teaches hydroxypropyl methylcellulose, methylcellulose, and hydroxyethyl cellulose as exemplary thickeners that provide thickening and stability to cosmetic compositions (see pages 15-16). The Handbook further teaches that fragrances are used in almost all types of cosmetic and toiletry products and are included to enhance the use characteristics and convey or support the marketing concept or brand image to the end-user. Patchouli oil and sandalwood oil are taught as common cosmetic fragrance additives (see pages 348 and 361).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the cellulose esters of Biener as hydroxypropyl methylcellulose or hydroxyethyl cellulose, as taught by the Handbook of Cosmetic Science and Technology, because of the expectation of achieving a thickened and stabilized cosmetic composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add patchouli oil or sandalwood oil, as taught by the Handbook of Cosmetic Science and Technology, to the composition of Biener because of the expectation of achieving a cosmetic product that enhances the use characteristics and conveys or supports the marketing concept or brand image to the end-user.

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biener as applied to claims 1-2, 4-5, 10, 13, 14, 19, 20, 29 above, and further in view of Kyotaro et al. (JP 08-113530).

Biener is applied as discussed above. The reference does not teach Dead Sea Water.

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Kyotaro et al. teach compositions comprising Dead Sea water for beautifying the skin horny later, accelerating skin functions, restoring or improving the functions essentially possessed by the skin and keeping the skin in a normal state.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the salt water of Beiner for that taught by Kyotaro because of the expectation of achieving beautification of the skin horny later, accelerating skin functions, restoring or improving the functions essentially possessed by the skin and keeping the skin in a normal state, thus providing similar therapeutic effects to patients with psoriasis.

Claims 27, 28, 30, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riklis (WO 97/16155) in view of Beiner (4,943,432).

The instant claims are directed to a gel composition comprising Dead Sea water, solubilizer, gelling agent/viscosity modifier, and deionized water to 100%

Riklis teaches lotions/creams comprising any combination of deionized water, wheatgerm oil (hydrophobic active), emulsifying vegetable wax (solubilizer), carbomer (gelling agent), lavender oil (fragrance), salicylic acid (hydrophilic active), Dead Sea water, and other ingredients. The reference fails to teach gel forms preferred percent weights of active agents. See pg. 7.

Beiner teaches compositions resembling Dead Sea water. It is taught that it is advantageous to apply the salt solution in gel instead of fluid form because gel composition forms can isolate certain parts of the body for and from treatment. The gel of Beiner are transparent (clear). See Col. 4, lines 4-8.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of Riklis in the form of a gel, as taught by Beiner, because of the expectation of achieving a composition that can target specific parts of the body and avoid specific parts of the body, for maximum therapeutic effect.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the percent weights of the instant invention as that of Riklis because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant argues, “Biener discloses a composition having salt water not exceeding 34% of the total mixture”. This argument is not persuasive. The Examiner respectfully points out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Applicant argues, “Biener expressly teaches away from the use of actual Dead Sea water”. This argument is not persuasive, as it is not commensurate in scope with independent claims 1 and 5, which do not require Dead Sea Water.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw

April 16, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER

6/1/03